DETAILED ACTION

Receipt of Response to Election/Restriction filed on January 15 2008is acknowledged. Claims 5, 11-17 and 25-34 were/stand cancelled. Claims 1-2, 18, 21 and 23-24 were amended. Claim 35 was added. Claims 1-4, 6-10, 18-24 and 35 are pending.

Information Disclosure Statement

The information disclosure statement filed March 6 2006, specifically EP 0136768, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Election/Restrictions

Applicant's election of Group I in the reply filed on January 15 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)). Claims 1-4, 6-10, 18-24 and 35 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "majority" in claim 35 is a relative term which renders the claim indefinite. The term "majority" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 2 depends from claim 35 and indicates at least 75% of the colloidal particles have diameters between 0.005 and 0.015 micrometers. However, it is unclear what constitutes a majority of the particles. Applicant has provided no guidance the lower limit of majority.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 8-10, 18-24, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. (US Patent No. 20030054046, cited on PTO Form 1449).

Applicant Claims

Applicant claims a hydrogel composition comprising a hydrophilic polymer dissolved in a composition of silver in water having a total concentration of silver of between about 5 and 40 parts per million, said silver in the form of colloidal silver particles having an interior of elemental silver and a surface of silver oxide wherein the composition manifest antimicrobial properties.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Burrell et al. is directed to the treatment of inflammatory skin conditions. Example 11, number 2 discloses carboxymethyl cellulose (CMC) fiber coated directed with a nanocrystalline silver coating. The CMC was then gelled in water. The gel had significant bactericidal effect against pseudomonas aeruginosa. The silver utilized is similar to those set forth in Example 1. Example 1 discloses preparation of nanocrystalline silver coatings. The coating consists of a silver base layer and a silver oxide top layer (example 1). Example 11 (number 3) utilizes alginate as the hydrocolloid polymer. It is disclosed that the concentrations of silver in solution will vary but generally range from 1 to 5000 μg/ml (1 to 5000 ppm) (paragraph 0054). The average grain size of example 1 is 10 nm. Silver containing gel (example 4) reduced

pseudomonas aeruginosa and staphylococcus aureus properties (paragraph 0242). Other hydrocolloid polymers listed as being suitable include algal extracts, seed extracts, or plant exudates such as gum arabic, guar gum, alginates etc. (paragraph 0156). It is disclosed that other ingredients can be disclosed including surface active agents (surfactants) and growth factors (paragraph 0179). It is disclosed that the ethanol can be added to a silver containing dressing to activate the coating (paragraph 0183). Exemplified is the treatment of adult acne with silver gel occluded by a hydrocolloid dressing (example 12).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Burrell et al. does not exemplify a hydrogel with a concentration of silver from 5 to 40 parts per million. Burrell et al. do not exemplify utilizing a gum as the hydrocolloid polymer. Burrell et al. do not exemplify utilizing other anti-microbial agents or additives in addition to the silver. However Burrell et al. discloses that concentrations of silver utilized include 1 to 5000 ppm, that suitable hydrocolloids include gums such as guar gum, and that surfactants, growth factors or ethanol can be added to the composition.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to vary the amount of silver utilized in the hydrogel. One of ordinary skill in the art would have been motivated to utilize an amount of silver from 1 to 5000 ppm because these are the amounts disclosed by Burrell et al. as being suitable. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5]**

It would have been obvious to one of ordinary skill in the art to utilize guar gum as the hydrocolloid polymer. One of ordinary skill in the art would have been motivated to utilize this polymer as it is disclosed a suitable hydrocolloid polymer to utilize. Additionally, one of ordinary skill in the art would have been motivated to replace the exemplified alginate with guar gum as both are taught by Burrell et al. as functional equivalents.

It would have been obvious to one of ordinary skill in the art to further add growth factors or surfactants or ethanol to the hydrogel. One of ordinary skill in the art would have been motivated to add any of these ingredients because all are disclosed by Burrell et al. as being suitable ingredients that can be included in the silver containing compositions.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. in view of Schonfeld et al. (US Patent No. 4646730).

Applicant Claims

Applicant further comprises hydrogen peroxide. The concentration is between about 1 % wght/v and about 3.0% wght/v.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Burrell et al. are set forth above. Specifically, Burrell et al. discloses silver containing hydrogels.

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Burrell et al. do not specify that hydrogen peroxide can be added to the silver containing hydrogel. However, this deficiency is cured by Schonfeld et al.

Schonfeld et al. is directed to color stabilized hydrogel dressing. Schonfeld discloses that hydrogen peroxide can be added to a silver containing hydrogel as a color stabilizing agent (column 2 lines 60-61). The amount of hydrogen peroxide is from about 0.25 to 1 % of the total weight of the gel (column 3, lines 50-53).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Burrell et al. and Schonfeld and utilize hydrogen peroxide. One of ordinary skill in the art would have been motivated to utilize hydrogen peroxide in order to provide color stabilization of a hydrogel as taught by Schonfeld et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-10, 18-24 and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7135195 in view of Burrell et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a hydrogel composition comprising a hydrophilic polymer dissolved in a composition of silver in water having a total concentration of silver of between about 5 and 40 parts per million, said silver in the form of colloidal silver particles having an interior of elemental silver and a surface of silver oxide wherein the composition manifest antimicrobial properties.

Patent ‘195 claims a composition of silver in water comprising a concentration of silver of between about 5 and 40 parts per million, the silver in the form of colloidal silver particles having an interior of elemental silver and a surface of silver oxide. The silver particles have a diameter greater than 0.005 micrometers and less than 0.015 micrometers. The composition exhibits antimicrobial properties. Patent ‘195 claims all the instant limitations in the dependent claims.

Patent ‘195 does not claim that the composition comprises a hydrophilic polymer and is in the form of a hydrogel. However, this deficiency is cured by Burrell et al. discloses that formulations of silver that are used to treat skin diseases like acne include hydrogels. The polymers utilized to create hydrogels include alginates, guar gum, and cellulose and derivatives (paragraphs 0154-0156 and 0220).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Patent '195 and Burrell et al. and formulate the composition of Patent '195 into a hydrogel. One of ordinary skill in the art would have been motivated to use this type of formulation because both Patent ‘195 and Burrell et al. are directed to utilizing silver containing compositions for the treatment of various anti-microbial diseases. The treatment of skin diseases such as acne would benefit from a topical application such as a hydrogel. Therefore, when utilizing the silver composition of Patent ‘195 for the treatment of acne one of ordinary skill in the art would have been motivated to formulate the composition into a hydrogel for easier application to the infected area.

Claims 1-4, 6-10, 18-24 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 118134081. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims are set forth above.

Copending '081 claims a composition of silver in water comprising a concentration of silver of between about 5 and 40 parts per million, the silver in the form of colloidal silver particles having an interior of elemental silver and a surface of silver oxide. The silver particles have a diameter greater than 0.005 micrometers and less than 0.015 micrometers. The composition exhibits antimicrobial properties. A further limitation is that the composition comprises hydrogel formed by dissolved a hydrophilic polymer into the composition of silver in water. Copending '081 claims all the instant limitations in the dependent claims.

Therefore, the scopes of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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